

What is claimed is:

1. An isolated outer membrane protein of *N. gonorrhoeae* having an apparent molecular weight of 85kDa and comprising an amino acid sequence selected from the group consisting of:
 - (a) SEQ ID NO: 2
 - (b) a fragment of (a);
 - (c) an analog of (a) or (b) characterized by having at least 80% homology with SEQ ID NO: 2; and
 - (d) a homolog of (a) or (b) characterized by having at least 80% homology with SEQ ID NO: 2.
2. The protein according to claim 1 which is a recombinant protein.
3. The protein according to claim 1 which is a synthetic protein.
4. The protein according to claim 1 which is fused to a second polypeptide or protein.
5. A nucleic acid sequence encoding the Omp85 of *N. gonorrhoeae* or a fragment thereof.
6. The nucleic acid sequence according to claim 5, selected from the group consisting of:
 - (a) SEQ ID NO: 1
 - (b) a sequence which hybridizes to (a) under stringent conditions;
 - (c) an allelic variant of any of (a) and (b);
 - (d) a fragment of any of (a) through (c); and
 - (e) a mutant of (a) through (d).

7. The nucleic acid sequence according to claim 6 which employs preference codons for expression in a selected host cell.
8. A nucleic acid molecule comprising a nucleic acid sequence encoding the Omp85 of *N. gonorrhoeae* or a fragment thereof under the control of suitable regulatory sequences which direct expression of said Omp 85 or fragment in a selected host cell.
9. The molecule according to claim 8 which is a plasmid.
10. A host cell transformed with the molecule according to claim 8.
11. A recombinant virus comprising the molecule of claim 8.
12. A method of recombinantly expressing the Omp85 of *N. gonorrhoeae* or a fragment thereof comprising the steps of culturing a host cell of claim 10 under conditions which permit expression of said protein or peptide.
13. The method according to claim 12 further comprising the step of isolating said expressed protein from said cell or said cell medium.
14. The method according to claim 12 wherein said Omp85 protein is a fusion protein.
15. The method according to claim 12 wherein said Omp85 protein is a mutant protein.
16. A method for preparing an Omp85 protein of *N. gonorrhoeae* or fragment thereof comprising chemically synthesizing said protein or fragment.

17. A diagnostic reagent comprising a nucleic acid sequence selected from the group consisting of:
- (a) a nucleic acid sequence encoding Omp85 of *N. gonorrhoeae*, isolated from cellular materials with which it is naturally associated;
 - (b) SEQ ID NO:1 or a sequence complementary thereto;
 - (c) a fragment of any of (a) or (b) comprising at least 15 nucleotides in length;
 - (d) a sequence which hybridizes to (a) through (c) under stringent conditions;
 - (e) an allelic variant of any of (a) through (d);
 - (f) a mutant of (a) through (e);
 - (g) a sequence encoding Omp85 or a fragment thereof fused to a sequence encoding a second protein;
- and a detectable label which is associated with said sequence.
18. An isolated antibody which binds Omp85 of *N. gonorrhoeae* or a fragment thereof.
19. The antibody according to claim 18, which is specific for Omp85 of *N. gonorrhoeae* or a fragment thereof.
20. The antibody according to claim 18 produced by administering to a vertebrate host an Omp85 protein of *N. gonorrhoeae* or fragment thereof.
21. The antibody according to claim 18, isolated by immunizing said host with the protein of claim 1.
22. The antibody according to claim 18 which is selected from the group consisting of a chimeric antibody, a humanized antibody, a monoclonal antibody and a polyclonal antibody.

23. An anti-idiotype antibody specific for the antibody of claim 18.
24. A diagnostic reagent comprising the antibody according to claim 18 and a detectable label.
25. A vaccine composition comprising an effective amount of a Omp85 protein of *N. gonorrhoeae*, a fusion protein or fragment thereof and a pharmaceutically acceptable carrier.
26. The composition according to claim 25 which is a polyvalent vaccine further comprising at least one other antigen or fragment thereof from a heterologous pathogenic species or a homologous pathogenic species.
27. The composition according to claim 25 wherein said Omp85 protein or fragment and said other antigen are in the form of a fusion protein.
28. A vaccine composition comprising an effective amount of a nucleic acid sequence encoding the Omp85 protein of *N. gonorrhoeae*, a fusion protein, or a fragment thereof and a suitable nucleic acid delivery vehicle.
29. The composition according to claim 28 which is a polyvalent vaccine further comprising at least one other nucleic acid sequence encoding an antigen or fragment thereof from a heterologous pathogenic species or a homologous pathogenic species.
30. The composition according to claim 29 wherein said nucleic acid sequence encodes said Omp85 protein or fragment and said other antigen in the form of a fusion protein

31. A method of vaccinating a human or animal against non-symptomatic gonococcal infection or symptomatic disease comprising administering to said human or animal a composition comprising an effective amount of the composition of claim 25.

32. A method of vaccinating a human or animal against non-symptomatic gonococcal infection or symptomatic disease comprising administering to said human or animal a composition comprising an effective amount of the composition of claim 28.

33. A method for diagnosing non-symptomatic gonococcal infection or symptomatic disease in a human or animal comprising the steps of:
contacting an Omp85 antigen optionally associated with a detectable label or a homolog thereof with a biological sample from a human subject to be diagnosed, wherein the presence of naturally occurring antibodies to *N. gonorrhoeae* in said sample permits the formation of an antigen-antibody complex, and
analyzing said sample for the presence of said complex, which indicates infection with *N. gonorrhoeae*.

34. A method for diagnosing non-symptomatic gonococcal infection or symptomatic disease in a human or animal comprising the steps of:
contacting an Omp85 antibody, optionally associated with a detectable label, with a biological sample from a human subject to be diagnosed, wherein the presence of naturally occurring *N. gonorrhoeae* Omp85 in said sample permits the formation of an antigen-antibody complex, and
analyzing said sample for the presence of said complex, which indicates infection with *N. gonorrhoeae*.

35. A method for diagnosing non-symptomatic gonococcal infection or symptomatic disease in a human or animal comprising the steps of:

employing a nucleic acid sequence encoding all or a portion of an Omp85 antigen or an Opm85 antibody, optionally associated with a detectable label, as a probe which, when in contact with a biological sample from a human subject to be diagnosed, enables detection of infection by hybridization or amplification of nucleic acid sequences of *N. gonorrhoeae* Omp85 in said sample.

36. A therapeutic composition useful in treating humans or animals with non-symptomatic gonococcal infection or symptomatic disease comprising at least one anti-Omp85 antibody and a suitable pharmaceutical carrier.

37. A method for treating non-symptomatic gonococcal infection or symptomatic disease in a mammalian host comprising administering an effective amount of a composition according to claim 36.

38. A kit for diagnosing infection with *N. gonorrhoeae* in a human or animal comprising a component selected from the group consisting of an Omp85 protein of *N. gonorrhoeae*, a fragment thereof, an anti-Omp85 antibody of claim 16, a nucleic acid sequence encoding an Omp85 protein of *N. gonorrhoeae*, and a fragment thereof, and suitable detectable labels.

39. A method of identifying compounds which specifically bind to Omp85 of *N. gonorrhoeae* or a fragment thereof, comprising the steps of contacting said Omp85 protein or fragment thereof with a test compound to permit binding of the test compound to Omp85; and determining the amount of test compound which is bound to Omp85.

40. A compound identified by the method of claim 39.

41. An isolated outer membrane protein of *N. meningitidis* having an apparent molecular weight of 85kDa and comprising an amino acid sequence selected from the group consisting of:
- (a) SEQ ID NO. 4
 - (b) a fragment of (a);
 - (c) an analog of (a) or (b) characterized by having at least 80% homology with SEQ ID NO. 4, and
 - (d) a homolog of (a) or (b) characterized by having at least 80% homology with SEQ ID NO. 4.
42. The protein according to claim 41 which is a recombinant protein.
43. The protein according to claim 41 which is a synthetic protein.
44. The protein according to claim 41 which is fused to a second polypeptide or protein.
45. A nucleic acid sequence encoding the Omp85 of *N. meningitidis* or a fragment thereof.
46. The nucleic acid sequence according to claim 45, selected from the group consisting of:
- (a) SEQ ID NO. 3
 - (b) a sequence which hybridizes to (a) under stringent conditions;
 - (c) an allelic variant of any of (a) and (b);
 - (d) a fragment of any of (a) through (c), and
 - (e) a mutant of (a) through (d).
47. The nucleic acid sequence according to claim 45 which employs preference codons for expression in a selected host cell.

48. A nucleic acid molecule comprising a nucleic acid sequence encoding the Omp85 of *N. meningitidis* or a fragment thereof under the control of suitable regulatory sequences which direct expression of said Omp 85 or fragment in a selected host cell.

49. The molecule according to claim 48, which is a plasmid.

50. A host cell transformed with the molecule of claim 48.

51. A recombinant virus comprising the molecule of claim 48.

52. A method of recombinantly expressing the Omp85 of *N. meningitidis* or a fragment thereof comprising the steps of culturing a recombinant host cell transformed with a nucleic acid sequence encoding said protein or fragment under conditions which permit expression of said protein or peptide.

53. The method according to claim 52 further comprising the step of isolating said expressed protein from said cell or said cell medium.

54. The method according to claim 52 wherein said Omp85 protein is a fusion protein.

55. The method according to claim 52 wherein said Omp85 protein is a mutant protein.

56. A method for preparing an Omp85 protein of *N. meningitidis* or fragment thereof comprising chemically synthesizing said protein or fragment.

57. A diagnostic reagent comprising a nucleic acid sequence selected from the group consisting of:

- (a) a nucleic acid sequence encoding Omp85 of *N. meningitidis*, isolated from cellular materials with which it is naturally associated;
 - (b) SEQ ID NO:3 or a sequence complementary thereto;
 - (c) a fragment of any of (a) or (b) comprising at least 15 nucleotides in length;
 - (d) a sequence which hybridizes to (a) through (c) under stringent conditions;
 - (e) an allelic variant of any of (a) through (d);
 - (f) a mutant of (a) through (e);
 - (g) a sequence encoding Omp85 or a fragment thereof fused to a sequence encoding a second protein;
- and a detectable label which is associated with said sequence.

58. An isolated antibody which binds Omp85 of *N. meningitidis* or a fragment thereof.

59. The antibody according to claim 58 which is specific for Omp85 of *N. meningitidis* or a fragment thereof.

60. The antibody according to claim 58 produced by administering to a vertebrate host an Omp85 protein of *N. meningitidis* or fragment thereof.

61. The antibody according to claim 58, isolated by immunizing said host with the protein of claim 41.

62. The antibody according to claim 58 which is selected from the group consisting of a chimeric antibody, a humanized antibody, a monoclonal antibody and a polyclonal antibody.

63. An anti-idiotype antibody specific for the antibody of claim 58.
64. A diagnostic reagent comprising the antibody according to claim 58 and a detectable label.
65. A vaccine composition comprising an effective amount of a Omp85 protein of *N. meningitidis*, a fusion protein or fragment thereof and a pharmaceutically acceptable carrier.
66. The composition according to claim 65 which is a polyvalent vaccine further comprising at least one other antigen or fragment thereof from a heterologous pathogenic species or a homologous pathogenic species.
67. The composition according to claim 65 wherein said Omp85 protein or fragment and said other antigen are in the form of a fusion protein.
68. A vaccine composition comprising an effective amount of a nucleic acid sequence encoding the Omp85 protein of *N. meningitidis*, a fusion protein, or a fragment thereof and a suitable nucleic acid delivery vehicle.
69. The composition according to claim 68 which is a polyvalent vaccine further comprising at least one other nucleic acid sequence encoding an antigen or fragment thereof from a heterologous pathogenic species or a homologous pathogenic species.
70. The composition according to claim 68 wherein said nucleic acid sequence encodes said Omp85 protein or fragment and said other antigen in the form of a fusion protein

71. A method of vaccinating a human or animal against non-symptomatic meningococcal infection and symptomatic disease comprising administering to said human or animal a composition comprising an effective amount of the composition of claim 68.

72. A method of vaccinating a human or animal against non-symptomatic meningococcal infection and symptomatic disease comprising administering to said human or animal a composition comprising an effective amount of the composition of claim 68.

73. A method for diagnosing non-symptomatic meningococcal infection and symptomatic disease in a human or animal comprising the steps of:-
contacting an Omp85 antigen optionally associated with a detectable label or a homolog thereof with a biological sample from a human subject to be diagnosed, wherein the presence of naturally occurring antibodies to *N. meningitidis* in said sample permits the formation of an antigen-antibody complex, and
analyzing said sample for the presence of said complex, which indicates infection with *N. meningitidis*.

74. A method for diagnosing non-symptomatic meningococcal infection and symptomatic disease in a human or animal comprising the steps of:-
contacting an Omp85 antibody, optionally associated with a detectable label, with a biological sample from a human subject to be diagnosed, wherein the presence of naturally occurring *N. meningitidis* Omp85 in said sample permits the formation of an antigen-antibody complex, and
analyzing said sample for the presence of said complex, which indicates infection with *N.*

73. A method for diagnosing non-symptomatic meningococcal infection and symptomatic disease in a human or animal comprising the steps of:
- contacting an Omp85 antigen optionally associated with a detectable label or a homolog thereof with a biological sample from a human subject to be diagnosed, wherein the presence of naturally occurring antibodies to *N. meningitidis* in said sample permits the formation of an antigen-antibody complex, and
- analyzing said sample for the presence of said complex, which indicates infection with *N. meningitidis*.
74. A method for diagnosing non-symptomatic meningococcal infection and symptomatic disease in a human or animal comprising the steps of:
- contacting an Omp85 antibody, optionally associated with a detectable label, with a biological sample from a human subject to be diagnosed, wherein the presence of naturally occurring *N. meningitidis* Omp85 in said sample permits the formation of an antigen-antibody complex, and
- analyzing said sample for the presence of said complex, which indicates infection with *N. meningitidis*.
75. A method for diagnosing non-symptomatic meningococcal infection and symptomatic disease in a human or animal comprising the steps of:
- employing a nucleic acid sequence encoding all or a portion of an Omp85 antigen or an Opm85 antibody, optionally associated with a detectable label, as a probe which, when in contact with a biological sample from a human subject to be diagnosed, enables detection of infection by hybridization or amplification of nucleic acid sequences of *N. meningitidis* Omp85 in said sample.
76. A therapeutic composition useful in treating humans or animals with non-symptomatic meningococcal infection and symptomatic disease comprising at least one anti-*N. meningitidis* Omp85 antibody and a suitable pharmaceutical carrier.

77. A method for treating non-symptomatic meningococcal infection and symptomatic disease in a mammalian host comprising administering an effective amount of a composition according to claim 76.
78. A kit for diagnosing infection with *N. meningitidis* in a human or animal comprising a component selected from the group consisting of an Omp85 protein of *N. meningitidis*, a fragment thereof, an anti-Omp85 antibody of claim 53, a nucleic acid sequence encoding an Omp85 protein of *N. meningitidis*, and a fragment thereof, and suitable detectable labels.
79. A method of identifying compounds which specifically bind to Omp85 of *N. meningitidis* or a fragment thereof, comprising the steps of contacting said Omp85 protein of *N. meningitidis* or fragment with a test compound to permit binding of the test compound to Omp85, and determining the amount of test compound which is bound to Omp85.
80. A compound identified by the method of claim 79.
81. A method of identifying a pharmacomimetic of Omp85 of *N. gonorrhoeae* or *N. meningitidis* comprising the steps of:
- (a) identifying a compound which binds to Omp85 by screening said Omp85 against a battery of compounds;
 - (b) performing computer modelling of the three dimensional structure of said Omp85 or said binding compound of step (a) to identify a compound with the same three dimensional structure as Omp85 or its binding compound; and
 - (c) screening said selected compound in a biological assay.

- 1 An immunogenic composition comprising

(a) a polypeptide or peptide selected from the group consisting of

i. the polypeptide of SEQ ID NO 2, a homolog thereof, or a fragment thereof of at least eight consecutive amino acids in length, which induces antibodies to *N. gonorrhoeae* in a mammalian subject, and

ii. a homolog of SEQ ID NO 4, or a fragment thereof of at least eight consecutive amino acids in length, which induces antibodies to *N. gonorrhoeae* in a mammalian subject, and

(b) a pharmaceutically acceptable carrier.

2 The composition according to claim 1, wherein said polypeptide (a) is a sequence that contains one to four conservative amino acid replacements in the amino acid sequence of SEQ ID NO 2 or 4.

3 The composition according to claim 1, wherein said polypeptide (a) is a homolog having at least 85% identity with the sequence of SEQ ID NO 2 or 4.

4 The composition according to claim 1, wherein said polypeptide or peptide is fused to a second polypeptide or protein.

5 The composition according to claim 4, wherein said second polypeptide or protein is an antigen or fragment thereof from a heterologous pathogenic species or a homologous pathogenic species.

6 The composition according to claim 1, wherein said fragment comprises an amino acid sequence within amino acids 720 to 745 of SEQ ID NO 2 or 4.

7. The composition according to claim 1, wherein said fragment comprises an amino acid sequence within amino acids 1 to 178 of SEQ ID NO. 2 or 4.
8. An immunogenic composition comprising:
- (a) a nucleic acid sequence selected from the group consisting of
- i. a nucleic acid sequence of SEQ ID NO. 1, a sequence capable of hybridizing thereto under stringent conditions, or a fragment thereof, which, when expressed in a host cell, produces a polypeptide that induces antibodies to *N. gonorrhoeae*,
- ii. a nucleic acid sequence of SEQ ID NO. 3, a sequence capable of hybridizing thereto under stringent conditions, or a fragment thereof, which, when expressed in a host cell, produces a polypeptide that induces antibodies to *N. meningitidis*, and
- (b) a pharmaceutically acceptable carrier.
9. The composition according to claim 8, wherein said nucleic acid sequence has at least 85% identity with the sequence of SEQ ID NO. 1 or 3.
10. The composition according to claim 8, wherein said nucleic acid sequence encoding said polypeptide is fused to a second nucleic acid sequence encoding a second polypeptide or protein.
11. The composition according to claim 8, further comprising a suitable nucleic acid delivery vehicle.
12. The composition according to claim 10, wherein said second polypeptide is at least one other antigen or fragment thereof from a heterologous pathogenic species or a homologous pathogenic species.

14. The composition according to claim 8, wherein said fragment encodes an amino acid sequence within amino acids 720 to 745 of SEQ ID NO. 2 or 4

15. The composition according to claim 8, wherein said fragment encodes an amino acid sequence within amino acids 1-178 of SEQ ID NO. 2 or 4

16. A diagnostic composition comprising at least one component selected from the group consisting of

- (a) the polypeptide of SEQ ID NO. 2, a homolog thereof, or a fragment thereof of at least eight consecutive amino acids in length, which induces antibodies to *N. gonorrhoeae* in a mammalian subject;
- (b) the polypeptide of SEQ ID NO. 4, a homolog thereof, or a fragment thereof of at least eight consecutive amino acids in length, which induces antibodies to *N. gonorrhoeae* in a mammalian subject;
- (c) a nucleic acid sequence of SEQ ID NO. 1, a sequence capable of hybridizing thereto under stringent conditions, or a fragment thereof, which, when expressed in a host cell, produces a polypeptide that induces antibodies to *N. gonorrhoeae*;
- (d) a nucleic acid sequence of SEQ ID NO. 3, a sequence capable of hybridizing thereto under stringent conditions, or a fragment thereof, which, when expressed in a host cell, produces a polypeptide that induces antibodies to *N. meningitidis*, and
- (e) a polypeptide of (a) or (b) that contains, or a nucleic acid sequence of (c) or (d) that encodes, one to four conservative amino acid replacements in the amino acid sequence of SEQ ID NO. 2 or 4;
- (f) a polypeptide of (a) or (b) that contains, or a nucleic acid sequence of (c) or (d) that encodes, a polypeptide that has at least 85% identity with the sequence of SEQ ID NO. 2 or 4;
- (g) a polypeptide of (a) or (b) that contains, or a nucleic acid sequence of (c) or (d) that encodes, a second polypeptide or protein;

(h) a polypeptide fragment of (a) or (b) that contains, or a nucleic acid sequence of (c) or (d) that encodes, a peptide fragment that comprises an amino acid sequence within amino acids 720 to 745 of SEQ ID NO 2 or 4,

(i) a polypeptide of (a) or (b) that contains, or a nucleic acid sequence of (c) or (d) that encodes, a peptide fragment that comprises an amino acid sequence within amino acids 1 to 178 of of SEQ ID NO 2 or 4, and
a suitable detectable label or detection system associated therewith

17 The compositions according to claim 16, which is a diagnostic reagent

18 The composition according to claim 16, with is a diagnostic kit

18 A nucleic acid molecule comprising (a) a nucleic acid sequence of SEQ ID NO 1, a sequence capable of hybridizing thereto under stringent conditions, or a fragment thereof, which, when expressed in a host cell, produces a polypeptide that induces antibodies to *N. gonorrhoeae*, or (b) a nucleic acid sequence of SEQ ID NO 3, a sequence capable of hybridizing thereto under stringent conditions, or a fragment thereof, which, when expressed in a host cell, produces a polypeptide that induces antibodies to *N. meningitidis*, under the control of suitable regulatory sequences which direct expression of said polypeptide in said host cell.

19 A host cell transformed with the molecule of claim 18